

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Daniel J. Potter	Confirmation No.	7602
Serial No.:	10/609,194	Examiner:	Aamer S. Ahmed
Filed:	06/26/2003	Art Unit:	3763
Docket No.:	11533US.00		
For:	Tearable Hemostasis Valve And Splittable Sheath		

AMENDMENT AND REQUEST FOR RECONSIDERATION

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being
filed electronically on:

July 31, 2006

Estella Pineiro

Dear Sir:

In response to the Office Action dated April 06, 2006, which was made final, and for which a one-month extension of time is herein requested, please amend the above-identified application as follows.

In The Claims:

Amend the claims as follows:

1. (Currently Amended) A tearable hemostasis valve, comprising:
a valve body;
a first grip tab attached to said valve body at a first point;
a second grip tab attached to said valve body at a second point;
a score line disposed on said valve body between said first and second points;
a first membrane disposed within said valve body; and
a snap-fit arrangement coupled to a distal end of said valve body, wherein the snap and fit arrangement is adapted to couple onto ~~[[a]]~~ an annular hub of a tubular medical device.
2. (Original) The valve of claim 1, wherein said first membrane is bonded to said valve body.
3. (Original) The valve of claim 1, wherein said first membrane is integrally formed with said valve body.
4. (Original) The valve of claim 3, wherein said first point and said second point are the same.
5. (Original) The valve of claim 4, wherein: said first membrane comprises a material of a first durometer; and said valve body comprises a material of a second durometer, said second durometer higher than said first durometer.
6. (Original) The valve of claim 5, further comprising a score in said first membrane.
7. (Original) The valve of claim 5, further comprising a second membrane disposed within said valve body parallel to said first membrane.

8. (Original) The valve of claim 7, wherein said first and second membranes are self-sealing.

9. (Previously Amended) The valve of claim 8, wherein said snap-fit arrangement comprises:

a cavity disposed in said valve body; and an annular sidewall defining an opening in communication with said cavity, wherein a diameter of said opening is less than a diameter of said cavity.

10. (Original) The valve of claim 9, wherein said annular sidewall is flexible.

11. (Original) The valve of claim 9, wherein said opening is located below said cavity.

12. (Original) The valve of claim 9, wherein said opening is located along one side of said cavity.

13. (Withdrawn) A method for removing a sheath from a patient's body, comprising:

splitting a hemostasis valve attached to said sheath along a lateral axis of said valve;

splitting said sheath along a longitudinal axis of said sheath; and removing said valve from said sheath; and

pulling said sheath from said patient's body while splitting said sheath.

14. (Withdrawn) The method of claim 13, wherein the step of removing said valve from said sheath comprises sliding said valve away from said sheath along a split formed along said lateral axis.

15. (Withdrawn) The method of claim 14, wherein the step of splitting said sheath along a longitudinal axis of said sheath comprises: exerting force on at least one sheath wing away from said longitudinal axis; and tearing said sheath along a score line parallel to said longitudinal axis.

16. (Withdrawn) A splittable sheath, comprising:
a flexible body defining a hollow cavity therein;
means for splitting said sheath operably connected to said flexible body at least one sheath wing operably connected to said means for splitting;
a neck affixed to said flexible body and having a first diameter; and
a hub affixed to said neck, said hub having a second diameter greater than said first diameter.

17. (Withdrawn) The splittable sheath of claim 16, wherein said neck and hub define a pathway from said cavity to an exterior of said sheath.

18. (Withdrawn) The splittable sheath of claim 17, wherein said means for splitting comprises at least one score line.

19. (Withdrawn) The splittable sheath of claim 18, wherein said at least one score line extends parallel to a longitudinal axis of said sheath.

20. (Withdrawn) The splittable sheath of claim 19, wherein said at least one score line extends along the entirety of said neck, hub, and body.

REMARKS

It is respectfully requested that the Office enter the above claim amendments and following remarks before considering the RCE filed concurrently herewith. Claims 1-20 are currently pending in this application. Applicant has withdrawn claims 13-20 from consideration in response to a Restriction Requirement.

In the Office action, dated April 6, 2006, which was made final, the Examiner rejected claims 1-12 under 35 U.S.C §103(a) as being anticipated by U.S. Patent Application No. 20010049499 to Lui et al. in view of U.S. Patent 6,083,207 to Heck. Applicant respectfully traverses this rejection.

The Examiner admits that Lui et al. do not disclose or suggest a snap fit arrangement coupled to a distal end of a valve body as recited in Applicant's claimed invention. The Examiner alleges however that Heck discloses a snap fit arrangement coupled to a distal end of a valve body that is adapted to couple onto a hub of tubular medical device. The Examiner further alleges that it would have been obvious to one of skill in the art to modify the device of Liu et al. by incorporating the snap fit arrangement taught by Heck. Applicant respectfully disagrees.

It is well understood that there must be some suggestion in the references that they be combined to support an obviousness rejection. Merely picking and choosing among various references is not permitted, and doing so amounts to no more than mere hindsight reconstruction. One of ordinary skill in the art must be motivated by the teachings to combine the references, without using applicants' claimed invention as a guide. Further, the strongest rationale for combining references is a recognition, either expressly or impliedly, in the prior art, that some advantage or expected beneficial result would be produced by the proposed combination of references. In re Sernaker, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983).

The Examiner suggests that the motivation to combine Lui et al. and Heck is to form a secure attachment between the valve and tubular medical device. The medical valve of Lui et al. includes a locking lip located at the proximal end of a proximal receiving chamber that helps hold the dilator hub therein. (Lui et al., FIGS. 9 and 31-33; paragraph 52). Thus in Lui et al. a dilator hub passes through a passageway in the

valve body into a proximal receiving chamber that is configured to accept a dilator hub forming a secure attachment between the valve and the tubular medical device. Thus, Liu et al. include a mechanism for forming a secure attachment between the valve and tubular medical device and there is no motivation to combine the valve of Liu et al. with the locking mechanism of Heck. Therefore, combining the references amounts to hindsight reconstruction based upon the teaching of Applicant's claimed invention, which is improper.

Further, Applicant's claimed invention as recited in independent claim 1 is directed towards a tearable hemostasis valve having a snap-fit arrangement coupled to a distal end of a valve body, wherein the snap and fit arrangement is adapted to couple onto an annular hub of a tubular medical device. (Underlining added for emphasis only). Applicant respectfully submits that neither Lui et al. nor Heck disclose or suggest the recited claim elements.

Rather, the medical valve of Lui et al. includes a locking lip located at a proximal end of a proximal receiving chamber that helps hold the dilator hub therein. (Lui et al., FIGS. 9 and 31-33; paragraph 52). Further, the hemostasis valve system of Heck includes a hemostasis valve housing and an adaptor system secured to the partitioned hemostasis valve housing, by which a splittable sheath (i.e. tubular medical device) can be secured to the partitioned hemostasis valve system, for example, as shown in FIGS. 1 and 2. Heck further discloses that in a preferred embodiment, the adaptor system (18) includes a pair of sides which when brought together, create a structure which holds a T-shaped top of the splittable sheath. (Heck, col. 8, lines 40-49). The adaptor system of Heck then forms a tight fit around the T-shaped handle of the splittable sheath to hold it securely in place.

Thus, the tubular device of Heck does not include a snap and fit arrangement adapted to couple onto an annular hub of a tubular medical device as recited in claim 1 of the present invention. Accordingly, Applicant respectfully submits that claim 1 is novel and unobvious over Lui et al. and Heck and is therefore allowable. Applicant further submits that claims 2-12 that depend from claim 1 is allowable as is claim 1 and for additional limitations recited therein.

PATENT

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

7-31-04

Date

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